

## PATENT

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	Rothenberg
Serial No.	10/759,658
Filed	January 16, 2004
Art Unit	1647
Confirmation No.	8032
Examiner:	Bunner
Title	REGULATION OF ALLERGEN INDUCED GENE
Atty. Docket No.	CMC 162

Cincinnati OH 45202

February 7, 2007

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

#### DECLARATION OF MARC E. ROTHENBERG, M.D., Ph.D. PURSUANT TO 37 CFR §1.132

I, Marc E. Rothenberg M.D., Ph.D., declare as follows:

1. I am the named inventor in the above-identified patent application.

2. I received my degree as a Doctor of Medicine from Harvard Medical School, and my degree as a Doctor of Philosophy from Harvard Medical School. I have 18 years of experience in medical research. In particular, I have 17 years of both clinical and research experience in the field of pulmonary physiology, pathology, and molecular biology, which is the subject of this application. I have read the Office Action of November 14, 2006 and understand the Examiner's position.

3. I disagree that the terms "pulmonary inflammatory process" and "chronic repair process" are indefinite. One skilled in the art would know that pulmonary inflammation and chronic repair are characterized by at least one of the following markers: altered genomic expression, changed pulmonary histology, and/or increased pulmonary secretions. I have shown each of these markers in my application.

4. I disagree that the term "clinical status" is indefinite. Using the teachings of my specification, one skilled in the art would appreciate that "clinical status" describes a process using RELM $\alpha$  and RELM $\beta$  levels to determine the presence of a pulmonary inflammatory process or chronic repair process in patients. One skilled in the art would know that "clinical status" describes a patient as either having or not having some degree of pulmonary inflammatory process or a chronic repair process.

5. I disagree with the Examiner's characterization that asthma is not an adequate description of "an entire genus of methods for determining the level of RELM $\beta$  to assess a patient's clinical status for a genus of pulmonary diseases and a genus of pulmonary inflammatory processes or chronic repair processes." One skilled in the art would appreciate that the asthmatic lung is a prototypical pulmonary disease characterized by having an inflammatory process and a chronic repair process.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the subject application or any patent issued thereon.

Feb 7, 2007

Date

Marc E. Rothenberg  
Marc E. Rothenberg, M.D., Ph.D.